

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 4:21-cv-1329
)	
JOSEPH R. BIDEN, JR., <i>et al.</i> ,)	
)	
Defendants.)	

**DEFENDANTS' MEMORANDUM IN SUPPORT OF
THEIR MOTION TO DISMISS THE FIRST AMENDED COMPLAINT**

INTRODUCTION

The Supreme Court effectively resolved this case a year ago. In *Biden v. Missouri*, 142 S. Ct. 647 (2022), the Court held that the vaccination rule at issue here is within the Secretary’s statutory authority, and it explicitly rejected Plaintiffs’ claims that the rule is arbitrary and capricious, procedurally invalid, and contrary to law. Plaintiffs’ constitutional challenges were briefed and argued to the Supreme Court, and that Court implicitly rejected those claims as well. In light of the Supreme Court’s decision, the Eighth Circuit has vacated this Court’s preliminary injunction order, and the Supreme Court has denied Plaintiffs’ petition for a writ of certiorari. In a last-ditch effort to breathe some life into this case, a year after filing their original Complaint, and ten months after the Supreme Court issued its stay, Plaintiffs have amended their Complaint. They again fail to state a single cognizable claim: Nine of the eleven claims in the First Amended Complaint repeat or offer only minor variations on Plaintiffs’ allegations in the original Complaint. Plaintiffs try to raise a Non-Delegation claim here for the first time, but such a claim was already briefed to the Supreme Court and implicitly rejected. Plaintiffs’ only other new claim—that “changed circumstances” justify vacating the vaccination rule—is improper as a matter of law. This Court should accordingly dismiss the First Amended Complaint in its entirety.

BACKGROUND

I. Prior proceedings of this litigation.

After this Court issued a preliminary injunction against the enforcement of the vaccination rule, ECF No. 28, Defendants filed a notice of appeal, ECF No. 29. Both this Court and the Eighth Circuit denied motions for a stay of the injunction pending appeal. ECF Nos. 35, 38. Defendants then filed applications in the Supreme Court for a stay of this Court’s preliminary injunction and for a stay of a preliminary injunction entered against the same rule by the Western District of Louisiana.

In their briefing before the Supreme Court, Plaintiffs contended that the Secretary lacked statutory authority to issue the vaccination rule, *see* Resp. to Appl. for a Stay at 10, *Biden v. Missouri*, No. 21A240 (U.S. Dec. 30, 2021), and that the relevant statutes should be read narrowly because a broader reading would approach the limits of Congress’s Spending Clause power, *id.* at 24. They further contended

that the rule violated 42 U.S.C. § 1395 insofar as it sought to control health care facilities' personnel decisions. *Id.* at 18-19.

Plaintiffs also argued that the vaccination rule was arbitrary and capricious because, in their view, the Secretary had failed to consider that the rule might exacerbate shortages in the health care workforce; the rule had an irrationally broad scope; the Secretary had arbitrarily rejected various alternatives; the rationale for the rule was pretextual; and the Secretary had failed to consider the reliance interests of various parties, including rural health care providers, in the status quo ante. *Id.* at 24-31. In addition, Plaintiffs asserted that the Secretary violated the procedural requirements of the Administrative Procedure Act ("APA") and the Medicare statute by issuing the rule without first providing for a period of notice and comment. *Id.* at 32.

On January 13, 2022, the Supreme Court granted the stay applications and, as explained below, effectively resolved the merits of this case in Defendants' favor. *Biden v. Missouri*, 142 S. Ct. 647 (2022). Following the Supreme Court's decision, the Eighth Circuit vacated the preliminary injunction in this case, and remanded the case to this Court for further proceedings. ECF No. 52. Plaintiffs filed a petition for a writ of certiorari. The Supreme Court denied the petition, without noted dissent, on October 3, 2022. *Missouri v. Biden*, 143 S. Ct. 94 (2022) (mem.).

Upon remand, Defendants filed a Motion to Dismiss the Complaint on November 2, 2022. ECF No. 68. Plaintiffs then filed the First Amended Complaint on November 23, 2022. ECF No. 72 ("FAC"). By Order of this Court the First Amended Complaint was deemed the operative Complaint, and Defendants' Motion to Dismiss the original Complaint was denied as moot. ECF No. 74.

ARGUMENT

THE SUPREME COURT’S DECISION EFFECTIVELY FORECLOSES THE CLAIMS IN PLAINTIFFS’ FIRST AMENDED COMPLAINT.

In *Biden v. Missouri*, 142 S. Ct. 647 (2022), the Supreme Court stayed this Court’s preliminary injunction. In so ruling, the Court effectively resolved each of the issues presented in the original Complaint in Defendants’ favor. Plaintiffs’ minor revisions to some of their claims in the First Amended Complaint does not alter this fact. Accordingly, Defendants move to dismiss the First Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6).

I. The Supreme Court Has Decided the Statutory and Procedural Claims in Defendants’ Favor.

The Supreme Court held, *first*, that “the Secretary’s rule falls within the authorities that Congress has conferred upon him.” *Id.* at 652. The Secretary has the “general statutory authority to promulgate regulations ‘as may be necessary to the efficient administration of the functions with which [he] is charged.’” *Id.* at 650 (quoting 42 U.S.C. § 1302(a)). “One such function—perhaps the most basic, given the Department’s core mission—is to ensure that the healthcare providers who care for Medicare and Medicaid patients protect their patients’ health and safety.” *Id.* “To that end, Congress authorized the Secretary to promulgate, as a condition of a facility’s participation in the programs, such ‘requirements as [he] finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.’” *Id.* (quoting 42 U.S.C. § 1395x(e)(9)). The Court noted that, “[r]elying on these authorities, the Secretary has established long lists of detailed conditions with which facilities must comply to be eligible to receive Medicare and Medicaid funds.” *Id.* “Such conditions have long included a requirement that certain providers maintain and enforce an ‘infection prevention and control program designed . . . to help prevent the development and transmission of communicable diseases and infections.’” *Id.* at 650-51 (quoting 42 C.F.R. § 483.80).

The Court cited the Secretary’s findings that the rule “will substantially reduce the likelihood that healthcare workers will contract the virus and transmit it to their patients[.]” and that “a vaccine mandate is ‘necessary to promote and protect patient health and safety’ in the face of the ongoing

pandemic.” *Id.* at 652 (citing Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555, 61,557-58, 61,613 (Nov. 5, 2021)). The Court concluded that

[t]he rule thus fits neatly within the language of the statute. After all, ensuring that providers take steps to avoid transmitting a dangerous virus to their patients is consistent with the fundamental principle of the medical profession: first, do no harm. It would be the “very opposite of efficient and effective administration for a facility that is supposed to make people well to make them sick with COVID-19.”

Id. (quoting *Florida v. Dep’t of Health & Hum. Servs.*, 19 F.4th 1271, 1288 (11th Cir. 2021)). The vaccination rule thus “is a straightforward and predictable example of the ‘health and safety’ regulations that Congress has authorized the Secretary to impose.” *Id.* at 653.

The Supreme Court also rejected the argument that the rule runs afoul of the directive in 42 U.S.C. § 1395 that federal officials may not “exercise any supervision or control over the . . . manner in which medical services are provided, or over the selection [or] tenure . . . of any officer or employee of” any facility. *Biden v. Missouri*, 142 S. Ct. at 654. The Court observed that Plaintiffs’ “reading of section 1395 would mean that nearly every condition of participation the Secretary has long insisted upon is unlawful.” *Id.*

Second, the Court held that the Secretary had good cause to issue the vaccination rule as an interim final rule (“IFR”), because “the Secretary’s finding that accelerated promulgation of the rule in advance of the winter flu season would significantly reduce COVID-19 infections, hospitalizations, and deaths constitutes the ‘something specific,’ required to forgo notice and comment.” *Id.* (citations omitted). Further, the Court rejected the argument that “the two months the agency took to prepare a 73-page rule constitutes ‘delay’ inconsistent with the Secretary’s finding of good cause.” *Id.*

Third, the Supreme Court “agree[d] with the Secretary that he was not required to ‘consult with appropriate State agencies,’ 42 U.S.C. § 1395z, in advance of issuing the [IFR]. Consistent with the existence of the good cause exception, which was properly invoked here, consultation during the deferred notice-and-comment period is permissible.” *Id.*¹

¹ See also Declaration of Karen Tritz ¶¶ 7-12, ECF No. 47-1 (explaining that CMS conducted a deferred notice and comment period, received feedback from state agencies during that time, and took additional steps to consult with relevant state agencies).

Fourth, the Court “similarly concur[red] with the Secretary that he need not prepare a regulatory impact analysis discussing a rule’s effect on small rural hospitals when he acts through an interim final rule; that requirement applies only where the Secretary proceeds on the basis of a ‘notice of proposed rulemaking,’ followed by a ‘final version of [the] rule.’” *Biden v. Missouri*, 142 S. Ct. at 654 (quoting 42 U.S.C. § 1302(b)(1), (b)(2)).

Fifth, the Court held that the IFR is not arbitrary and capricious.

Given the rulemaking record, it cannot be maintained that the Secretary failed to “examine the relevant data and articulate a satisfactory explanation for” his decisions to (1) impose the vaccine mandate instead of a testing mandate; (2) require vaccination of employees with “natural immunity” from prior COVID-19 illness; and (3) depart from the agency’s prior approach of merely encouraging vaccination.

Id. at 653-54 (quoting *Motor Vehicle Mfrs. Assn. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 (1983)). The Court also disagreed “that the Secretary ‘entirely failed to consider’ that the rule might cause staffing shortages, including in rural areas.” *Id.* at 654 (quotation omitted). And it rejected the lower courts’ criticism of other parts of “the Secretary’s analysis, particularly concerning the nature of the data relied upon,” *id.*, noting that the courts’ role “is to ‘simply ensur[e] that the agency has acted within a zone of reasonableness.’” *Id.* (quoting *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021)).

Finally, the Court held that it “disagree[d] with respondents’ remaining contentions in support of the injunctions entered below.” *Id.* at 653. These remaining contentions included several constitutional arguments, as explained more fully below.

The Supreme Court’s decision effectively forecloses each claim in the First Amended Complaint that was previously raised. Just as in their original Complaint, Plaintiffs once again contend that the rule is arbitrary and capricious (Count I); that the Secretary lacked statutory authority for the rule (Count II); that the Secretary lacked good cause to issue the rule without notice and comment (Counts III, IV); that 42 U.S.C. §§ 1302 and 1395z required the Secretary to prepare a regulatory impact analysis and to consult with state agencies before issuing the rule (Counts V, VI); and that the rule is unconstitutional under the Spending Clause, the anti-commandeering doctrine, and the Tenth

Amendment (Counts VII-IX). The Supreme Court flatly rejected Plaintiffs' statutory and procedural claims. *Biden v. Missouri*, 142 S. Ct. at 652-54. As to Plaintiffs' constitutional claims, including Plaintiffs' new Non-Delegation claim (Count X), each was previously argued to the Supreme Court and the Court's rejection of "the respondents' remaining contentions," *id.* at 653, forecloses each of these claims as well.

Of note, the District Court for the Western District of Louisiana recently dismissed a nearly identical action brought by fourteen states challenging the IFR.² In the Report and Recommendation, which was adopted in full by the district court, the Magistrate Judge there explained that dismissal was appropriate because the "Supreme Court explicitly *addressed* all of the bases argued in support of the motion for preliminary injunction except for the constitutional claims." *Louisiana v. Becerra*, No. CV 3:21-03970, 2022 WL 17408035, at *5 (W.D. La. Nov. 3, 2022), *report and recommendation adopted*, No. CV 3:21-03970, 2022 WL 17405839 (W.D. La. Dec. 2, 2022). This Court should similarly hold that Plaintiffs' statutory and procedural claims in the First Amended Complaint, which were all previously raised and rejected, are foreclosed.

Plaintiffs may contend, as they did in their recently denied petition for a writ of certiorari, that the Supreme Court has not expressly resolved all of their procedural challenges to the vaccination rule. In their petition, they argued that *Biden v. Missouri* left open their claims that the Secretary had purportedly failed to consider certain "reliance interests," and that the rationale for the vaccination rule was pretextual. Pet. for Writ of Cert. at 25-30, *Missouri v. Biden*, No. 21-1463 (U.S. May 12, 2022). But Plaintiffs presented these same arguments to the Supreme Court in the proceedings on the stay

² State plaintiffs in the other two cases brought by states challenging the vaccination rule have voluntarily dismissed their cases. Texas moved to dismiss its complaint "in light of the Supreme Court's ruling in *Biden v. Missouri*." Pls.' Mot. for Dismissal, *Texas v. Becerra*, No. 21-cv-00229-Z, ECF No. 63 (N.D. Tex. Jan. 18, 2022). The court granted the motion, citing the Supreme Court's decision as good cause to do so. Order, *Texas v. Becerra*, No. 21-cv-00229-Z, ECF No. 66 (N.D. Tex. Jan. 19, 2022). Florida likewise dismissed its complaint "[g]iven the United States Supreme Court's decision in *Biden v. Missouri*." Notice of Dismissal, *Florida v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-2722-MCR-HTC, ECF No. 26 (N.D. Fla. Feb. 4, 2022). The remaining challenge to the vaccination rule, brought by an individual plaintiff, has also been dismissed. See *Griner v. Biden*, No. 2:22-CV-149-DAK-DBP, 2022 WL 7501065, at *9 (D. Utah, Oct. 13, 2022) (district court dismissing claim that vaccination rule violated due process rights, and reiterating the Supreme Court's holding that "the Secretary reasonably explained his decisions").

application, *see* Resp. to Appl. for a Stay at 27, *Biden v. Missouri*, No. 21A240 (U.S. Dec. 30, 2021), and the Supreme Court disposed of them in January 2022 without extended comment; *see Biden v. Missouri*, 142 S. Ct. at 653 (holding that the Court “disagree[d] with respondents’ remaining contentions in support of the injunctions entered below”). This holding is binding on this Court with respect to all of Plaintiffs’ “remaining contentions.”³ *Biden v. Missouri*, 142 S. Ct. at 653.

II. The Supreme Court’s Decision Effectively Resolves Plaintiffs’ Constitutional Claims in Defendants’ Favor.

Plaintiffs fare no better with their reasserted constitutional claims. Those claims, too, were briefed to the Supreme Court. Although this Court did not rely on Plaintiffs’ constitutional claims in issuing its preliminary injunction, the district court in the *Louisiana* case relied on the virtually identical constitutional claims raised there, and the *Louisiana* plaintiffs further argued to the Supreme Court that the rule exceeded Congress’s Spending Clause power, was impermissibly coercive, and was unconstitutional under the Non-Delegation Doctrine. *See* Resp. to Appl. for a Stay Pending Appeal at 1, 23-27, *Becerra v. Louisiana*, Nos. 21A240, 21A241 (U.S. Dec. 30, 2021). The *Louisiana* plaintiffs argued that, at a minimum, the Supreme Court should interpret the statute to avoid the asserted constitutional problems. *See id.* at 27. The Supreme Court, indicating that it “disagree[d] with respondents’ remaining contentions in support of the injunctions entered below,” *Biden v. Missouri*, 142 S. Ct. at 653, ruled in the Secretary’s favor and interpreted the statute to authorize the rule. Accordingly, the Court effectively resolved Plaintiffs’ constitutional claims, rendering futile any attempt to revive those same claims. *See Thompson v. Comm’r*, 821 F.3d 1008, 1011 (8th Cir. 2016) (law of the case doctrine establishes that “every question decided by the appellate court, whether expressly or by necessary implication, is

³ In any event, these claims lack merit. Plaintiffs’ claim with regard to “reliance interests” rests on the premise that the Secretary previously had a policy opposing staff vaccination requirements; no such policy existed. The agency had simply declined to adopt such a requirement at earlier stages of the pandemic and then reasonably changed course for reasons the Secretary fully explained. *See* 86 Fed. Reg. at 61,568. Likewise, Plaintiffs fail to identify any “significant mismatch” between the Secretary’s decision and the rationale he offered for it. *Dep’t of Com. v. New York*, 139 S. Ct. 2551, 2575 (2019); *see also Biden v. Texas*, 142 S. Ct. 2528, 2546-47 (2022) (requiring “an accumulation of ‘unusual circumstances’” to demonstrate such a mismatch (quoting *Dep’t of Com.*, 142 S. Ct. at 2575)). To the contrary, the Secretary forthrightly acknowledged that the rule would protect other members of the public in addition to patients. *See* 86 Fed. Reg. at 61,612. But those salutary effects of the rule are not evidence of pretext.

finally settled and determined”).

The District Court for the Western District of Louisiana agreed on this point. There, the Magistrate Judge explained that the state plaintiffs argued in their Supreme Court brief that the IFR “violated the Spending Clause, the Tenth Amendment, the non-delegation doctrine, and constitutionally intruded on the States’ police powers,” such that “the constitutional issues were also part of the record and presented to the Supreme Court for its consideration.” *Louisiana*, 2022 WL 17408035, at *5. Despite this extensive briefing, the Magistrate Judge recognized that the Supreme Court held instead that the “Secretary’s rule falls within the authorities that Congress has conferred upon him.” *Id.* (quoting *Biden v. Missouri*, 142 S. Ct. at 652). Accordingly, with the possible exception of the anti-commandeering claim, the Magistrate Judge determined that “the Supreme Court also implicitly or tacitly rejected the constitutional claims as well.” *Id.* The District Court held that the Magistrate Judge’s ruling was “correct” and dismissed the case. *Louisiana*, 2022 WL 17405839, at *1. Accordingly, Plaintiffs’ constitutional claims, including their newly raised Non-Delegation claim (Count Ten)—a claim brought and argued by the *Louisiana* plaintiffs—are foreclosed.

It is unsurprising that the Supreme Court disposed of the constitutional claims so easily. “Congress has authority under the Spending Clause to appropriate federal moneys to promote the general welfare” and “to see to it that taxpayer dollars appropriated under that power are in fact spent for the general welfare.” *Sabri v. United States*, 541 U.S. 600, 605 (2004) (citation omitted). Congress’s power to impose conditions on federal funds applies regardless of whether Congress legislates “in an area historically of state concern.” *Id.* at 608 n.*. Because these conditions on federal funds are “supported by affirmative constitutional grants of power to Congress [under the Spending Clause], [they are] not inconsistent with the Tenth Amendment.” *New York v. United States*, 505 U.S. 144, 173 (1992).

The Supreme Court’s decision also effectively forecloses Plaintiffs’ assertion that they lacked adequate notice that the Secretary might impose a funding condition like the vaccination rule. The Court explained that the rule “is not a surprising one.” *Biden v. Missouri*, 142 S. Ct. at 653. The Secretary “routinely imposes conditions of participation that relate to the qualifications and duties of healthcare

workers themselves,” and “[v]accination requirements are a common feature of the provision of healthcare in America,” *id.* Plaintiffs made no attempt to square their Spending Clause argument with the Secretary’s “longstanding litany of health-related participation conditions,” the validity of which Plaintiffs did not contest. *Id.* The Supreme Court’s conclusion that the rule “is a straightforward and predictable example of the ‘health and safety’ regulations that Congress has authorized the Secretary to impose,” *id.*, likewise effectively forecloses any contention that Congress’s grant of these authorities to the Secretary poses any issue under the Non-Delegation Doctrine. *See Bhatti v. Fed. Hous. Fin. Agency*, 15 F.4th 848, 854 (8th Cir. 2021).

Even if the anti-commandeering claim was not implicitly rejected by the Supreme Court, that claim is meritless as well. The vaccination rule imposes the same conditions on health care facilities that participate in the Medicare or Medicaid programs, no matter whether those facilities are privately-run or State-run. The Secretary did not run afoul of the anti-commandeering principle by imposing these conditions on equal terms. *See Murphy v. NCAA*, 138 S. Ct. 1461, 1478 (2018) (“The anticommandeering doctrine does not apply when Congress evenhandedly regulates an activity in which both States and private actors engage.”). This was the precise holding of the District Court in the Western District of Louisiana. The Magistrate Judge determined, and the District Court agreed, that because the vaccination rule “evenhandedly regulates the activity as to both public and private actors, [that] does not transgress the anti-commandeering principle.” *Louisiana*, 2022 WL 17408035, at *6; *see also Louisiana*, 2022 WL 17405839, at *1. This Court should conclude the same.

III. Count Eleven is Improper as a Matter of Law

In their final claim (Count XI), Plaintiffs erroneously argue that “changes in core circumstances” require this Court to vacate the vaccination rule. FAC ¶¶ 384-86. As a threshold matter, Plaintiffs fail to identify any cause of action permitting such a claim. While the Prayer for Relief references 28 U.S.C. § 2201, the Declaratory Judgment Act, *see* FAC Prayer for Relief ¶ H, this statute provides a “remedy, like a request for punitive damages; it is not an independent cause of action.” *Riley v. U.S. Fire Ins. Co.*, No. 4:21-CV-0192-DGK, 2022 WL 390837, at *4 (W.D. Mo. Feb. 8, 2022). “A successful action for declaratory judgment requires a viable underlying cause of action.” *Salau v.*

Denton, 139 F. Supp. 3d 989, 1012 (W.D. Mo. 2015) (citation omitted). Because Plaintiffs fail to identify any cause of action which could support a claim of “changes in core circumstances,” this claim necessarily fails.

Nor would the APA provide a basis for this claim. Arbitrary and capricious review does not permit courts to apply “hindsight derived from matters [that] occur[ed] after the[] adoption” of the challenged agency action. *SIH Partners LLLP v. Comm’r*, 923 F.3d 296, 301 (3d Cir. 2019); *see also Fearin v. Fox Creek Valley Watershed Conservancy Dist.*, 793 F.2d 1291 (6th Cir. 1986) (holding that a court may not “substitute [its] judgment, improved by the luxury of hindsight, for that of the [agency]”). It is a bedrock principle of administrative law that, under the APA, a reviewing court must confine its consideration to the “record that was before the Secretary *at the time he made his decision.*” *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971) (emphasis added); *see also Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44 (1985); *Voyageurs Nat’l Park Ass’n v. Norton*, 381 F.3d 759, 766 (8th Cir. 2004). As the Supreme Court explained in this very case, the role of courts is not to demand perfect predictive abilities, but “to ‘simply ensur[e] that the agency has acted within a zone of reasonableness.’” *Biden v. Missouri*, 142 S. Ct. at 654 (quoting *Prometheus Radio Project*, 141 S. Ct. at 1158). And based on the administrative record as it existed before the Secretary, the Supreme Court held that, “[g]iven the rulemaking record, it cannot be maintained that the Secretary [had] failed to examine the relevant data,” or that he had committed any other procedural or substantive violation. *Biden v. Missouri*, 142 S. Ct. at 653-54 (citation omitted). That holding remains binding on this Court.

Plaintiffs argue, on the basis of two decades-old decisions, that this Court should conduct a *de novo* evaluation of all current evidence related to COVID-19. *See* FAC ¶ 384 (citing *Am. Optometric Ass’n v. FTC*, 626 F.2d 896, 907 (D.C. Cir. 1980), and *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156 (1962)). But neither case supports Plaintiffs’ argument. First, the cited “change in circumstances” at issue in both cases was legal, not factual, and Plaintiffs here point to no analogous change of law that would undermine the vaccination rule. *See Air Prods. & Chems., Inc. v. FERC*, 650 F.2d 687, 705–06 (5th Cir. 1981) (explaining that in *Burlington Truck Lines* the Supreme Court issued a ruling that “clearly preempted what the [agency] was proposing to do,” and that in *American Optometric*

Association a new law “made illegal precisely the type of action which precipitated” the challenged agency action). Additionally, Plaintiffs’ cited cases involved remand for further consideration due to changes in the law that occurred “subsequent to administrative decision and *prior* to court decision.” *Am. Optometric Ass’n*, 626 F.2d at 907 (emphasis added) (quoting *Greater Boston Television Corp. v. FCC*, 463 F.2d 268, 283 (D.C. Cir. 1971)). Plaintiffs cite no authority supporting the notion that a lower court can effectively overturn a Supreme Court decision under the APA on account of purportedly changed factual circumstances. Finally, and most significantly, binding precedent precludes this Court from evaluating post-hoc evidentiary submissions, as the Court is “confined to the administrative record in deciding an appeal under the APA.” See *South Dakota v. U.S. Dep’t of Interior*, 423 F.3d 790, 802–03 (8th Cir. 2005) (explaining that this constraint exists precisely “in order to ‘preclude[] the reviewing court from conducting a de novo trial and substituting its opinion for that of the agency.’”) (citations omitted).

Plaintiffs’ invitation for this Court to weigh the developing scientific evidence relating to COVID-19, which post-dates the agency action at issue, would upend APA jurisprudence and permit *de novo* review of regulations promulgated years or decades prior, simply because a plaintiff alleges that certain facts have changed. Cf. *SIH Partners LLLP*, 923 F.3d at 302 (holding that such arguments “are not evidence that the regulations were arbitrary or capricious *at the time they were promulgated*”); *Airport Communities Coal. v. Graves*, 280 F. Supp. 2d 1207, 1213 (W.D. Wash. 2003) (explaining that for a court to consider “new information” that was not before the agency when it made its decision “would effectively transform [arbitrary and capricious] analysis into *de novo* review,” in violation of the APA).

While longstanding precedent precludes Plaintiffs from asserting this claim here, they are not without any avenue for doing so. An argument that “recent developments compel the amendment of an older regulation” may be reviewed “through [judicial] review of the denial of a petition to amend” submitted to the agency. See *Alon Refin. Krotz Springs, Inc. v. EPA*, 936 F.3d 628, 643 (D.C. Cir. 2019).⁴ In fact, in seeming recognition of the availability of this procedure, “many of the Plaintiff States joined

⁴ Indeed, *Geller v. FCC*, 610 F.2d 973, 979-80 (D.C. Cir. 1979), also cited by Plaintiffs, involved the denial of a “petition for new rulemaking.” See FAC ¶ 388.

a petition asking CMS to repeal” the vaccination rule. FAC ¶ 149. And the APA provides a mechanism for review of the agency’s determination on that petition. *See* 5 U.S.C. §§ 555(e); 706(2). But Plaintiffs bring no claim arising out of that petition, which is still under consideration at the agency. As a result, there is no valid claim before this Court regarding the alleged change in factual circumstances after issuance of the IFR.

CONCLUSION

For the foregoing reasons, the First Amended Complaint should be dismissed.

Dated: January 20, 2023

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director
Federal Programs Branch

/s/ Michael Drezner
MICHAEL L. DREZNER
Bar No. 83836(VA)
Trial Attorney

JULIE STRAUS HARRIS
Bar No. 1021298(DC)
Senior Trial Counsel

U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, DC 20530
Tel: (202) 514-4505
Fax: (202) 616-8470
Email: Michael.L.Drezner@usdoj.gov

Attorneys for Defendants